

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,

Plaintiff,

v.

AMERISOURCEBERGEN CORPORATION;  
AMERISOURCEBERGEN DRUG  
CORPORATION; and INTEGRATED  
COMMERCIALIZATION SOLUTIONS, LLC,

Defendants.

Case No. 2:22-cv-05209-GJP

**DEFENDANTS' ANSWER TO PLAINTIFF'S COMPLAINT  
WITH AFFIRMATIVE DEFENSES**

Defendants AmerisourceBergen Corporation (n/k/a Cencora, Inc.) ("ABC"), AmerisourceBergen Drug Corporation ("ABDC"), and Integrated Commercialization Solutions, LLC ("ICS" and together with ABC and ABDC "Defendants"), hereby submits their Answer and Affirmative Defenses to the Complaint filed by Plaintiff the United States of America ("Plaintiff") as follows:

1. Admitted in part; denied in part. Defendants admit that the opioid epidemic has had effects on the country, but further state that the extent and nature of those effects have varied over time and across the country. Defendants further admit that the United States of America ("Plaintiff") has filed this civil action against Defendants alleging violations of the suspicious order reporting provisions of the Controlled Substances Act ("CSA") and its implementing regulations. Defendants deny all remaining allegations in this paragraph, including that there is any basis "to hold [them] civilly liable." Defendants deny any and all liability to Plaintiff. Moreover, to the

extent Plaintiff seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

2. Denied. The allegations in this paragraph call for legal conclusions to which no response is required.

3. Denied. The allegations in this paragraph call for legal conclusions to which no response is required.

4. Denied. The allegations in this paragraph call for legal conclusions to which no response is required.

5. Denied. The allegations in this paragraph call for legal conclusions to which no response is required.

6. Denied.

7. Denied.

8. Denied.

9. Denied.

10. Denied.

11. Denied.

12. Denied. The allegations in this paragraph call for legal conclusions to which no response is required.

13. Admitted.

14. Admitted, subject to the clarification that effective August 30, 2023, ABC changed its name to Cencora, Inc.

15. Admitted.

16. Admitted.

17. Admitted in part; denied in part. Defendants admit only that ABDC and ICS are indirect subsidiaries of ABC. The remaining allegations in this paragraph contain legal arguments and conclusions to which no response is required.

18. Admitted in part; denied in part. Defendants admit only that ABC maintains its headquarters in Pennsylvania and that it employs CSRA personnel who are involved in aspects of Defendants' compliance functions. Given the vague and imprecise nature of the allegations regarding "various shared personnel and services," Defendants lack knowledge or information sufficient to admit or deny those allegations. Accordingly, those allegations are deemed denied. The remaining allegations in this paragraph contain legal arguments and conclusions to which no response is required.

19. Denied. The allegations in this paragraph are based upon and purport to characterize and interpret CSRA's charter, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the charter for a complete and accurate description of the contents of that document.

20. Denied. Given the vague and imprecise nature of the allegations in this paragraph, Defendants lack knowledge or information sufficient to admit or deny them. Accordingly, those allegations are deemed denied.

21. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

22. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

23. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

24. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. Defendants deny all of the remaining allegations in this paragraph.

25. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

26. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

27. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

28. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

29. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

30. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

31. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

32. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

33. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

34. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

35. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

36. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

37. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

38. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

39. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants admit that ABDC and ICS operate distribution facilities that are registered with the DEA.

40. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

41. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

42. Admitted in part; denied in part. Defendants admit only that registered distributors are part of the “closed” system of the pharmaceutical supply chain for controlled substances. Defendants deny all of the remaining allegations in this paragraph.

43. Denied.

44. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

45. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

46. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

47. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

48. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

49. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

50. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

51. Admitted in part; denied in part. Defendants admit only that the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (the “SUPPORT Act”) was signed into law on October 24, 2018. The remaining allegations in this paragraph contain legal arguments and conclusions to which no response is required.

52. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

53. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

54. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

55. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

56. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

57. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations and therefore deny them. By way of further response, various governmental reports have found that DEA investigators in the field have historically rarely if ever used suspicious order reports in the way that this allegation suggests.

58. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

59. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

60. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

61. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

62. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

63. Denied as stated. Defendants admit only that various ABC subsidiaries (not ABC itself) distribute controlled substances through DEA-registered distribution facilities.

64. Denied as stated. Defendants admit only that for the fiscal year ended on September 30, 2022, ABC reported revenue of approximately \$238 billion and gross profit of approximately \$8.3 billion in its Form 10-K filed with the United States Securities and Exchange Commission.

65. Denied as stated. Defendants admit that certain ABC subsidiaries distribute pharmaceuticals, including controlled substances, to thousands of customers throughout the United States through DEA-registered distribution facilities.

66. Denied as stated. Defendants admit that certain ABC subsidiaries including ABDC and ICS distribute pharmaceuticals, including controlled substances through DEA-registered distribution facilities, and that ABC itself is not a DEA registrant.

67. Denied as stated. Defendants admit that, as of the date of the Complaint, ABDC was the DEA registrant for 26 distribution centers.

68. Denied as stated. Defendants admit that, as of the date of the Complaint, ABDC had DEA-registered distribution centers in the locations set forth in this paragraph, except that ABDC has a distribution center in Amityville, New York, not North Amityville, New York.

69. Denied as stated. Defendants admit that ABDC previously operated ten DEA-registered distribution centers that have since been retired.

70. Denied as stated. Defendants admit that, as of the date of the Complaint, ICS was the DEA registrant for three distribution centers.

71. Denied as stated. Defendants admit that, as of the date of the Complaint, ICS had distribution centers in the locations set forth in this paragraph.



72. Admitted in part; denied in part. Defendants admit only that ABDC and ICS are indirect subsidiaries of ABC, are registered with the DEA to distribute opioids and other controlled substances, and have been so registered during the time relevant to this action. The remaining allegations in this paragraph contain legal arguments and conclusions to which no response is required.

73. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

74. Denied as stated. Defendants admit only that ABDC and ICS collectively receive tens of millions of orders annually for controlled substances from customers across the country. By way of further response, Plaintiff does not define what it means by an “order.” For purposes of this Answer, Defendants do not adopt any legal interpretation of what constitutes an “order” for purposes of Plaintiff’s claims.

75. Denied. The allegations in this paragraph are based upon and purport to characterize and interpret ABDC’s and ICS’s controlled substances distribution data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the controlled substances distribution data for a complete and accurate description of its contents.

76. Denied. The allegations in this paragraph are based upon and purport to characterize and interpret ABDC’s distribution data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the distribution data for a complete and accurate description of its contents.

77. Denied as stated. Defendants admit that, during the relevant time period, ABDC and ICS had as customers certain retail pharmacies that dispense prescription drugs to the public.

78. Denied as stated. Defendants admit that, during the relevant time period, ABDC and ICS had as customers certain chain pharmacies and certain independent pharmacies.

79. Defendants admit only that ABC did previously engage Consulting Firm 1 to provide consulting services in the past, but denies that any work performed by Consulting Firm 1 had any connection to opioids or controlled substances specifically. Defendants deny the remaining allegations in this paragraph.

80. Denied. Defendants lack knowledge or information about what documents Plaintiff has purported to review or the nature or basis for its purported profitability calculations and therefore cannot form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied. By way of further response, Defendants state that ABDC's business model does not involve the sale of specific or individual products, instead relying on a "market basket" approach; nor, in the ordinary course of business, does ABDC calculate or track profit margins at a product level, and for those reasons as well the allegation is denied. Defendants further state that, in ICS's primary capacity as a third-party logistics ("3PL") organization, ICS does not set the prices for the products it distributes; the profit margins for controlled substances are not higher than non-controlled substances; and that shipments to independent pharmacies comprise a small percentage of ICS's business. Defendants further state in response to this paragraph's definition of "relevant period" that to the extent plaintiff seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

81. Denied. Defendants lack knowledge or information about the nature or basis for Plaintiff's purported profitability calculations and therefore cannot form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied. By way of

further response, Defendants state that ABDC's business model does not involve the sale of specific or individual products, instead relying on a "market basket" approach; nor, in the ordinary course of business, does ABDC calculate or track profit margins at a product level, and for those reasons as well the allegation is denied.

82. Denied. Defendants lack knowledge or information about the nature or basis for Plaintiff's purported profitability calculations and therefore cannot form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied. By way of further response, Defendants state that ABDC's business model does not involve the sale of specific or individual products, instead relying on a "market basket" approach; nor, in the ordinary course of business, does ABDC calculate or track profit margins at a product level, and for those reasons as well the allegation is denied.

83. Denied. Defendants lack knowledge or information about the nature or basis for Plaintiff's purported profitability calculations and therefore cannot form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied. By way of further response, Defendants state that ABDC's business model does not involve the sale of specific or individual products, instead relying on a "market basket" approach; nor, in the ordinary course of business, does ABDC calculate or track profit margins at a product level, and for those reasons as well the allegation is denied. Defendants further state that, in ICS's primary capacity as a 3PL organization, ICS does not set the prices for the products it distributes; the profit margins for controlled substances are not higher than non-controlled substances; and that shipments to independent pharmacies comprise a small percentage of ICS's business.

84. Denied. Defendants lack knowledge or information about the nature or basis for Plaintiff's purported profitability calculations and therefore cannot form a belief regarding the

allegations in this paragraph. Accordingly, those allegations are deemed to be denied. By way of further response, Defendants state that ABDC's business model does not involve the sale of specific or individual products, instead relying on a "market basket" approach; nor, in the ordinary course of business, does ABDC calculate or track profit margins at a product level, and for those reasons as well the allegation is denied.

85. Denied. Defendants lack knowledge or information about the nature or basis for Plaintiff's purported profitability calculations and therefore cannot form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied. By way of further response, Defendants state that ABDC's business model does not involve the sale of specific or individual products, instead relying on a "market basket" approach; nor, in the ordinary course of business, does ABDC calculate or track profit margins at a product level, and for those reasons as well the allegation is denied.

86. Denied. Defendants lack knowledge or information sufficient to speak to the "prefer[ences]" of "many retail pharmacies" and therefore cannot form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

87. Denied as stated. Defendants admit that CSRA personnel carry out diversion control functions on behalf of ABDC and ICS, including filing suspicious order reports.

88. Denied. Defendants lack knowledge or information about what representations the allegations in this paragraph refer to and therefore cannot form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied. Moreover, the allegations in this paragraph purport to characterize and interpret CSRA's charter, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the charter for a complete and accurate description of its contents.

89. Admitted.

90. Denied. The allegations in this paragraph purport to characterize and interpret Defendants' policies and procedures, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the policies and procedures for a complete and accurate description of their contents.

91. Denied as stated. Defendants admit that CSRA personnel performed, among other things, ongoing customer due diligence and were involved in decisions to terminate particular customers' ability to purchase controlled substances.

92. Denied as stated. Defendants admit that CSRA personnel have notified particular ABDC and/or ICS customers of decisions terminating those customers' ability to purchase controlled substances.

93. Admitted in part; denied in part. Defendants admit that CSRA personnel have notified particular ABDC and/or ICS customers of decisions terminating those customers' ability to purchase controlled substances. To the extent the allegations in this paragraph purport to characterize and interpret letters to unidentified customers, which are in writing and speak for themselves, Defendants deny those allegations and respectfully refer the Court to the letters for a complete and accurate description of their contents.

94. Admitted in part; denied in part. Defendants admit that DEA was notified of certain terminations of controlled substances sales to customers. To the extent the allegations in this paragraph purport to characterize and interpret letters regarding unidentified customers, which are in writing and speak for themselves, Defendants deny those allegations and respectfully refer the Court to the letters for a complete and accurate description of their contents.

95. Denied as stated. Defendants admit that CSRA personnel were involved in reporting suspicious orders to the DEA.

96. Denied as stated. Defendants admit that in 2007 the DEA temporarily suspended the license of one of ABDC's Florida distribution centers to distribute controlled substances. Defendants state that the DEA reinstated the suspended license shortly thereafter. The allegations in this paragraph purport to characterize and interpret a 2007 administrative order, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the administrative order for a complete and accurate description of its contents.

97. Denied. The allegations in this paragraph purport to characterize and interpret unidentified "letters from DEA to ABDC and other distributors," which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the letters for a complete and accurate description of their contents.

98. Denied. The allegations in this paragraph purport to characterize and interpret a 2007 administrative order, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the administrative order for a complete and accurate description of its contents. By way of further response, Defendants incorporate by reference their response to paragraph 96 above.

99. Denied. The allegations in this paragraph purport to characterize and interpret a 2007 administrative order, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the administrative order for a complete and accurate description of its contents. By way of further response, Defendants incorporate by reference their response to paragraph 96 above.

100. Admitted in part; denied in part. ABDC admits that it entered into a settlement with DEA with no admission of liability and no monetary penalty after ABDC and DEA engaged in discussions and agreed upon a new order monitoring program. The allegations in this paragraph purport to characterize and interpret a settlement agreement, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the settlement agreement for a complete and accurate description of its contents.

101. Admitted in part; denied as stated in part. ABDC admits that it implemented a new order monitoring program in conjunction with DEA as a result of the settlement. The allegations in this paragraph purport to characterize and interpret a settlement agreement, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the settlement agreement for a complete and accurate description of its contents.

102. Admitted in part; denied as stated in part. ABDC admits that its new order monitoring program included updated components developed in conjunction with DEA. The allegations in this paragraph purport to characterize and interpret compliance policies, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the policies for a complete and accurate description of their contents.

103. Admitted in part; denied as stated in part. ABDC admits that its new order monitoring program developed in conjunction with DEA was designed to detect suspicious orders of controlled substances, report suspicious orders and to reject and not ship suspicious orders. Defendants lack knowledge or information about what representations the allegations in this paragraph refer to and therefore cannot form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

104. Denied.

105. Denied.

106. Denied as stated. Defendants admit that CSRA personnel carried out compliance functions for ABDC and ICS, including with respect to diversion control and suspicious order reporting.

107. Denied as stated. Defendants admit that CSRA personnel carried out diversion control functions that included, among other things, new customer due diligence, ongoing customer due diligence, and suspicious order monitoring and reporting.

108. Denied.

109. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret a budget or other financial records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those documents for a complete and accurate description of their contents.

110. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret ABDC's distribution data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the distribution data for a complete and accurate description of their contents.

111. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants lack



knowledge or information about the nature or basis for Plaintiff's purported calculations and therefore cannot form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied. Finally, the allegations purport to characterize and interpret a budget or other financial records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those documents for a complete and accurate description of their contents.

112. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. By way of further response, CSRA's budgets are in writing and speak for themselves.

113. Denied. The allegations in this paragraph purport to characterize and interpret a budget or other financial records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those documents for a complete and accurate description of their contents.

114. Denied. The allegations in this paragraph purport to characterize and interpret a budget or other financial records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those documents for a complete and accurate description of their contents.

115. Denied.

116. Denied.

117. Denied. The allegations in this paragraph contain arguments and legal conclusions to which no response is required. To the extent a response is required, the allegations purport to characterize and interpret policies and procedures, which are in writing and speak for themselves.

Accordingly, Defendants deny those allegations and respectfully refer the Court to the policies and procedures for a complete and accurate description of their contents.

118. Denied. The allegations in this paragraph purport to characterize and interpret policies and procedures, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the policies and procedures for a complete and accurate description of their contents.

119. Denied. The allegations in this paragraph purport to characterize and interpret policies and procedures and due diligence questionnaires (including the “Form 590”), which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those documents for a complete and accurate description of their contents.

120. Denied. By way of further response, the purpose and use of the Form 590 is described in Defendants’ diversion control policies and procedures, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the policies and procedures for a complete and accurate description of their contents.

121. Denied as stated. By way of further response, Defendants state that numerous circumstances and factors may potentially be indicative of diversion, that no one circumstance or factor is dispositive, and that instead Defendants look to the totality of the circumstances when assessing every customer. Further responding, Defendants state that wholesale distributors are not afforded those police powers reserved solely for law enforcement, and therefore unlike law enforcement agencies Defendants are rarely, if ever, able to conclusively determine that a customer has or is engaged in the actual diversion of controlled substances.

122. Denied. The allegations in this paragraph purport to characterize and interpret policies and procedures and due diligence questionnaires (including the “Form 590”), which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those documents for a complete and accurate description of their contents.

123. Denied as stated. Defendants admit that the data requested from customers is one of many pieces of information Defendants may use as part of their new customer and ongoing customer due diligence efforts. Defendants deny all remaining allegations in this paragraph.

124. Denied. The allegations in this paragraph purport to characterize and interpret policies and procedures, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those policies and procedures for a complete and accurate description of their contents.

125. Admitted in part; denied in part. Defendants admit only that CSRA sometimes requested dispensing data from existing customers and sent auditors to customers as part of its due diligence efforts. Defendants deny all remaining allegations in this paragraph.

126. Denied. Defendants lack knowledge or information about what representations the allegations in this paragraph refer to and therefore cannot form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

127. Denied. The allegations in this paragraph contain argument and legal conclusions to which no response is required. To the extent a response is required, Defendants deny that they did not follow their policies and procedures and further deny that any alleged failure to follow their policies and procedures would be a basis for imposing liability.

128. Denied.

129. Admitted in part; denied in part. Defendants admit that sales representatives have assisted in collecting Form 590s and other information from customers and prospective customers at the direction and for the use of CSRA personnel. Defendants deny the remaining allegations in this paragraph.

130. Denied. The allegations in this paragraph refer to compensation policies and programs that are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those policies and programs for a complete and accurate description of their contents.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

135. Denied. The allegations in this paragraph refer to internal audit documentation that is in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those documents for a complete and accurate description of their contents. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

136. Denied as stated. Defendants admit that CSRA conducted a "590 Validation Project" to obtain Form 590s from certain customers.

137. Denied as stated. Defendants admit only that the "590 Validation Project" was completed over several years and that the progress of the project was tracked in spreadsheets,

which are in writing and speak for themselves. Defendants deny all remaining allegations in this paragraph.

138. Denied. The allegations in the first sentence in this paragraph refer to communications from CSRA's Vice President for Corporate Security and Diversion Control that are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those communications for a complete and accurate description of their contents. Defendants deny the allegations in the second sentence of this paragraph.

139. Denied.

140. Denied.

141. Denied.

142. Denied.

143. Denied.

144. Admitted in part; denied in part. Defendants admit only that CSRA sometimes requested dispensing data from existing customers and sent auditors to customers as part of its due diligence efforts. Defendants deny all remaining allegations in this paragraph.

145. Denied.

146. Denied.

147. Denied.

148. Denied.

149. Denied as stated. Defendants admit that, in 2007, ABDC developed and implemented, with the DEA's knowledge and involvement, a new order monitoring program that included a computerized component and a human review component. Defendants deny all remaining allegations in this paragraph.

150. Admitted.

151. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

152. Denied as stated. Defendants admit that in 2007, ABDC developed and implemented, with the DEA's knowledge and involvement, a new order monitoring program that included a computerized component and a human review component. That order monitoring program, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the order monitoring program. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

153. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

154. Denied as stated. Defendants admit that in 2007, ABDC developed and implemented, with the DEA's knowledge and involvement, a new order monitoring program that included a computerized component and a human review component. That order monitoring program, including the computer-based algorithms, evolved over time, and the details are set forth

in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the order monitoring program. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

155. Denied as stated. Defendants admit that in 2007, ABDC developed and implemented, with the DEA's knowledge and involvement, a new order monitoring program that included a computerized component and a human review component. That order monitoring program, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the order monitoring program. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

156. Denied as stated. Defendants admit that in 2007, ABDC developed and implemented, with the DEA's knowledge and involvement, a new order monitoring program that included a computerized component and a human review component. That order monitoring program, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of

Interrogatories, for a description of the order monitoring program. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

157. Denied as stated. Defendants admit that in 2007, ABDC developed and implemented, with the DEA's knowledge and involvement, a new order monitoring program that included a computerized component and a human review component. That order monitoring program, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the order monitoring program. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

158. Denied as stated. Defendants admit that in 2007, ABDC developed and implemented, with the DEA's knowledge and involvement, a new order monitoring program that included a computerized component and a human review component. That order monitoring program, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the order monitoring program. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.



159. Denied as stated. Defendants admit that in 2007, ABDC developed and implemented, with the DEA's knowledge and involvement, a new order monitoring program that included a computerized component and a human review component. That order monitoring program, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the order monitoring program. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

160. Denied as stated. Defendants admit that in 2007, ABDC developed and implemented, with the DEA's knowledge and involvement, a new order monitoring program that included a computerized component and a human review component. That order monitoring program, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the order monitoring program. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

161. Denied as stated. Defendants admit that in 2007, ABDC developed and implemented, with the DEA's knowledge and involvement, a new order monitoring program that included a computerized component and a human review component. Defendants further admit

that ABDC's order monitoring program included policies and procedures for considering customer requests to adjust thresholds on a case-by-case basis. The order monitoring program, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the order monitoring program. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

162. Denied. The allegations in this paragraph regarding the percentage of flagged orders purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. Defendants deny all remaining allegations in this paragraph. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

163. Denied.

164. Denied as stated. Defendants admit that in 2007, ABDC developed and implemented, with the DEA's knowledge and involvement, a new order monitoring program that included a computerized component and a human review component. That order monitoring program, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents previously produced to Plaintiff, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this

paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the order monitoring program. Moreover, to the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

165. Denied.

166. Denied.

167. Denied.

168. Denied.

169. Admitted in part; denied in part. Defendants admit that, in 2014, ABDC began work to enhance its existing order monitoring program with a revised order monitoring program, sometimes referred to as the ROMP. By way of further response, ABDC notified the DEA of those efforts and invited the DEA to participate, but the DEA declined. Defendants deny all remaining allegations in this paragraph.

170. Denied.

171. Admitted.

172. Admitted in part; denied in part. Defendants admit only that Consulting Firm 2 conducted a process review of CSRA. The allegations in this paragraph purport to characterize and interpret a report prepared by Consulting Firm 2 which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the report for a complete and accurate description of its contents.

173. Denied. The allegations in this paragraph purport to characterize and interpret a report prepared by Consulting Firm 2 which is in writing and speaks for itself. Accordingly,

Defendants deny those allegations and respectfully refer the Court to the report for a complete and accurate description of its contents.

174. Denied. The allegations in this paragraph refer to a report prepared by Consulting Firm 2 which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the report for a complete and accurate description of its contents.

175. Denied as stated. Defendants admit only that Consulting Firm 2 was engaged to assist with the design and implementation of the ROMP.

176. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. Moreover, Defendants lack knowledge or information to form a belief as to the truth of the allegations in this paragraph, which relate to what a third party, Consulting Firm 2, purportedly “came to understand.” Accordingly, those allegations are deemed to be denied.

177. Denied. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Defendants state that individuals working on the ROMP were aware of the requirements set forth in 21 C.F.R. §1301.74(b). By way of further response, Defendants state that the DEA had not at the time—and to this day still has not—provided any meaningful guidance to Defendants or the industry overall on what constitutes an order of “unusual size” or “unusual frequency” or an order “deviating substantially from a normal pattern.”

178. Denied.

179. Denied.

180. Denied as stated. Defendants admit that the ROMP, as originally implemented, contained three thresholds: a Cumulative Volume Threshold, an Order Size Threshold, and a Fail-

Safe Threshold. The ROMP, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the ROMP.

181. Denied as stated. Defendants admit that the ROMP, as originally implemented, contained three thresholds: a Cumulative Volume Threshold, an Order Size Threshold, and a Fail-Safe Threshold. The ROMP, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the ROMP.

182. Denied as stated. Defendants admit that the ROMP, as originally implemented, contained three thresholds: a Cumulative Volume Threshold, an Order Size Threshold, and a Fail-Safe Threshold. The ROMP, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the ROMP.

183. Denied as stated. Defendants admit that the ROMP, as originally implemented, contained three thresholds: a Cumulative Volume Threshold, an Order Size Threshold, and a Fail-Safe Threshold. The ROMP, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and

speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the ROMP.

184. Denied as stated. Defendants admit that the ROMP, as originally implemented, contained three thresholds: a Cumulative Volume Threshold, an Order Size Threshold, and a Fail-Safe Threshold. Defendants further admit that the ROMP, when originally implemented, flagged orders for further review that exceeded at least two thresholds. The ROMP, including the computer-based algorithms, evolved over time, and the details are set forth in policies, procedures, and other documents, which are in writing and speak for themselves. Accordingly, Defendants deny as stated the allegations in this paragraph, and respectfully refer the Court to those documents, as well as Defendants' Responses to Plaintiff's First Set of Interrogatories, for a description of the ROMP.

185. Denied.

186. Denied.

187. Denied.

188. Denied.

189. Denied. The allegations in this paragraph purport to characterize and interpret communications from Consulting Firm 2, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those communications for a complete and accurate description of their contents.

190. Denied. The allegations in this paragraph purport to characterize and interpret communications from Consulting Firm 2, which are in writing and speak for themselves.

Accordingly, Defendants deny those allegations and respectfully refer the Court to those communications for a complete and accurate description of their contents.

191. Denied.

192. Denied.

193. Denied.

194. Denied.

195. Admitted in part; denied in part. Defendants admit only that the ROMP included policies and procedures for considering customer requests to adjust thresholds on a case-by-case basis. Defendants deny all remaining allegations in this paragraph.

196. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

197. Denied. Defendants deny the allegations in the first sentence of this paragraph. The remaining allegations in this paragraph purport to characterize and interpret ABDC's order data and suspicious order reporting data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to that data for a complete and accurate description of their contents.

198. Denied.

199. Denied.

200. Denied.

201. Denied.

202. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's

claim for civil penalties prior to that date. Moreover, the allegations in this paragraph purport to characterize and interpret “internal analyses,” which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those analyses for a complete and accurate description of their contents.

203. Denied. The allegations in this paragraph purport to characterize and interpret ABDC’s order data and suspicious order reporting data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to that data for a complete and accurate description of their contents.

204. Denied.

205. Denied. The allegations in this paragraph purport to characterize and interpret communications which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those communications for a complete and accurate description of their contents.

206. Denied.

207. Denied.

208. Denied.

209. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

210. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

211. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

212. Denied.



213. Denied. The allegations in this paragraph purport to characterize and interpret policies and procedures which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those policies and procedures for a complete and accurate description of their contents.

214. Denied. The allegations in this paragraph purport to characterize and interpret policies and procedures which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those policies and procedures for a complete and accurate description of their contents.

215. Denied. The allegations in this paragraph purport to characterize and interpret policies and procedures which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those policies and procedures for a complete and accurate description of their contents.

216. Denied. The allegations in this paragraph purport to characterize and interpret policies and procedures which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those policies and procedures for a complete and accurate description of their contents.

217. Denied. The allegations in this paragraph purport to characterize and interpret policies and procedures, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those policies and procedures for a complete and accurate description of their contents.

218. Denied.

219. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for

civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret policies and procedures, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those policies and procedures for a complete and accurate description of their contents.

220. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

221. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret communications from Consulting Firm 2, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those communications for a complete and accurate description of their contents.

222. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret communications from Consulting Firm 2, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those communications for a complete and accurate description of their contents.

223. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

224. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

225. Admitted in part; denied in part. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that the Diversion Control team reviewed ABDC orders for drug families classified as "high risk" during the time period alleged, as well as other orders. Defendants deny all remaining allegations in this paragraph.

226. Denied. The allegations in this paragraph purport to characterize and interpret a policy document, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the policy for a complete and accurate description of its contents.

227. Denied as stated. By way of further response, Defendants state that the number of orders reviewed by members of the Diversion Control team is reflected in the order monitoring program data.

228. Denied.

229. Denied.

230. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's

claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret an employee's performance evaluation, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the performance evaluation for a complete and accurate description of its contents.

231. Denied.

232. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret an employee's performance evaluation, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the performance evaluation for a complete and accurate description of its contents.

233. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph. Accordingly, they are deemed to be denied.

234. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret order monitoring program data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the data for a complete and accurate description of its contents.

235. Denied.

236. Denied. The allegations in this paragraph purport to characterize and interpret a purported policy document, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the document for a complete and accurate description of its contents.

237. Denied. By way of further response, Defendants incorporate by reference their responses to the allegations in Section III(B) above.

238. Denied. The allegations in this paragraph purport to characterize and interpret a purported policy document, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the document for a complete and accurate description of its contents.

239. Denied. The allegations in this paragraph contain argument and legal conclusions to which no response is required. To the extent a response is required, Defendants deny that they did not follow their policies and procedures and further deny that any alleged failure to follow their policies and procedures would be a basis for imposing liability.

240. Denied.

241. Admitted in part; denied in part. Defendants admit that certain subsidiaries used different computer systems for their order monitoring programs and that certain employees reviewing orders may not have had access to all systems. Defendants deny all remaining allegations in this paragraph.

242. Denied. By way of further response, Defendants incorporate by reference their response to paragraph 241 above.

243. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's

claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret materials prepared by Consulting Firm 2, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those materials for a complete and accurate description of their contents.

244. Denied. By way of further response, Defendants state that several members of the Diversion Control team formerly worked at the DEA, including the head of the Diversion Control team who had nearly three decades of DEA experience before coming to ABC. Defendants further state that Defendants have provided and continue to provide both formal and on-the-job training to their associates related to controlled substances and diversion control.

245. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

246. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret materials prepared by Consulting Firm 2, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those materials for a complete and accurate description of their contents.

247. Denied.

248. Denied.

249. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

250. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

251. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret suspicious order reporting data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the data for a complete and accurate description of its contents.

252. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

253. Denied. The allegations in this paragraph purport to characterize and interpret a policy, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the policy for a complete and accurate description of its contents.

254. Admitted in part; denied in part. Defendants admit that ICS developed and maintained an order monitoring program, which was separate from the order monitoring programs used by ABDC. Defendants deny all remaining allegations in this paragraph.

255. Denied as stated. Defendants admit that ICS's legacy order monitoring program was in use for ICS's 3PL business through November 2019.

256. Denied.

257. Denied.

258. Denied as stated. Defendants admit that ICS orders held for review were placed on "51 holds."

259. Denied. The allegations in this paragraph purport to characterize and interpret policies, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the policies for a complete and accurate description of their contents.

260. Denied. The allegations in this paragraph purport to characterize and interpret policies, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the policies for a complete and accurate description of their contents.

261. Denied.

262. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret policies, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the policies for a complete and accurate description of their contents.



263. Denied. The allegations in this paragraph contain legal conclusions and argument to which no response is required. To the extent any response is required, Defendants deny the allegations in this paragraph.

264. Denied.

265. Denied.

266. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret suspicious order reporting records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

267. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. By way of further response, Defendants incorporate their responses to the purported "example" below.

268. Denied as stated. Defendants admit that, in November 2019, ICS began to roll out a new order monitoring program that uses third-party software.

269. Denied. The allegations in this paragraph contain legal conclusions and argument to which no response is required. To the extent any response is required, Defendants deny the allegations in this paragraph.

270. Denied. The allegations in this paragraph contain legal conclusions and argument to which no response is required. To the extent any response is required, Defendants deny the allegations in this paragraph.

271. Denied. The allegations in this paragraph contain legal conclusions and argument to which no response is required. To the extent any response is required, Defendants deny the allegations in this paragraph.

272. Denied. The allegations in this paragraph contain legal conclusions and argument to which no response is required. To the extent any response is required, Defendants deny the allegations in this paragraph.

273. Denied. The allegations in this paragraph contain legal conclusions and argument to which no response is required. To the extent any response is required, Defendants deny the allegations in this paragraph.

274. Denied. The allegations in this paragraph contain legal conclusions and argument to which no response is required. To the extent any response is required, Defendants deny the allegations in this paragraph.

275. Denied. By way of further response, Defendants incorporate their responses to the purported “examples” below.

276. Denied. By way of further response, Defendants incorporate their responses to the purported “examples” below.

277. Denied. By way of further response, Defendants incorporate their responses to the purported “examples” below.

278. Admitted.

279. Admitted in part; denied in part. Defendants admit only that Pharmacy 1 was a customer of ICS and ABDC for controlled substances for only part of the period identified in this paragraph and entirely before October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. The remaining allegations in this paragraph purport to characterize and interpret ABDC's and ICS's distribution data for Pharmacy 1, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the distribution data for a complete and accurate description of their contents.

280. Denied. The allegations in the first sentence purport to characterize and interpret public records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the public records for a complete and accurate description of their contents. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of this paragraph. Accordingly, those allegations are deemed to be denied.

281. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

282. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations of

this paragraph are denied insofar as they purport to characterize and interpret internal communications, reports, and records from Distributor 2, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those documents for a complete and accurate description of their contents. Defendants lack knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

283. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations of this paragraph are denied insofar as they purport to characterize and interpret internal communications, reports, and records from Distributor 2, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those documents for a complete and accurate description of their contents. Defendants lack knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

284. Admitted in part; denied in part. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that Pharmacy 1 completed a business application on December 30, 2015. Defendants deny all remaining allegations in this paragraph.

285. Admitted in part; denied in part. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is

required, Defendants admit only that Virtual Manufacturer 1 contracted with ICS for services related to the distribution of Virtual Manufacturer 1's products. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

286. Admitted in part; denied in part. Defendants admit only that Virtual Manufacturer 1 contracted with ICS for services related to the distribution of Levorphanol and Abstral, which are FDA-approved controlled substances with accepted medical uses. By way of further response, DEA's scheduling process formally attributes characteristics to scheduled substances. Defendants deny all remaining allegations in this paragraph.

287. Denied. The allegations in this paragraph purport to characterize and interpret the FDA approval and indications for Abstral, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the Abstral FDA approval and indications for a complete and accurate description of their contents.

288. Denied. The allegation in this paragraph regarding Abstral bearing "an FDA-required label" calls for a conclusion of law to which no response is required. The remaining allegations in this paragraph purport to characterize and interpret a drug label, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the drug label for a complete and accurate description of its contents.

289. Admitted in part; denied in part. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that Pharmacy 1 submitted a Form 590 to ICS. The remaining allegations in this paragraph purport to characterize and interpret the Form 590, which is in writing

and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the Form 590 for a complete and accurate description of its contents.

290. Admitted in part; denied in part. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that CSRA's then-Director of Diversion Control received due diligence materials for Pharmacy 1 and approved Pharmacy 1's account set up. Defendants deny all remaining allegations in this paragraph.

291. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

292. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret internal communications, reports, and records from Distributor 2, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those documents for a complete and accurate description of their contents.

293. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's

claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that ICS began distributing products to Pharmacy 1 in February 2016. Defendants deny all remaining allegations.

294. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

295. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret Pharmacy 1's Form 590 and ICS's distribution data for Pharmacy 1, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the Form 590 and distribution data for a complete and accurate description of their contents.

296. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

297. Admitted in part; denied in part. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is

required, Defendants admit only that Pharmacy 1 submitted an increase request form. Defendants deny all remaining allegations in this paragraph.

298. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret distribution and suspicious order reporting records for Pharmacy 1, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

299. Admitted in part; denied in part. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that Pharmacy 1 submitted a Form 590 in August 2016 seeking approval to purchase controlled substances from ABDC. Defendants deny all remaining allegations in this paragraph.

300. Denied as stated. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that members of CSRA conducted due diligence on Pharmacy 1 and approved Pharmacy 1 to purchase controlled substances from ABDC.

301. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. The allegations in this paragraph purport to characterize



and interpret Pharmacy 1's Form 590, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the Form 590 for a complete and accurate description of its contents.

302. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret due diligence communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the due diligence communications for a complete and accurate description of their contents.

303. Denied as stated. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that members of CSRA conducted due diligence on Pharmacy 1 and approved Pharmacy 1 to purchase controlled substances from ABDC.

304. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date.

305. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

306. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

307. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

308. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

309. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications and ROMP data, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications and ROMP data for a complete and accurate description of their contents.

310. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

311. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret ABDC's order data and order monitoring program records for Pharmacy 1, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to that data for a complete and accurate description of their contents.

312. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret suspicious order reporting records for Pharmacy 1, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

313. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations

purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

314. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

315. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications and distribution data, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications and distribution data for a complete and accurate description of their contents. By way of further response, Defendants state that Pharmacy 1 was sent a termination letter in May 2018, at which point the pharmacy immediately sought reconsideration of the decision and supplied additional documentation regarding its ordering.

316. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret suspicious order reporting records for Pharmacy 1, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and

respectfully refer the Court to those records for a complete and accurate description of their contents.

317. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret suspicious order reporting records for Pharmacy 1, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

318. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret suspicious order reporting records for Pharmacy 1, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

319. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret ABDC's and ICS's order monitoring program data and suspicious order reporting data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to that data for a complete and accurate description of their contents.

320. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret the May 17, 2018 termination letter, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the letter for a complete and accurate description of its contents.

321. Denied as stated. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that they did not block controlled substances sales to Pharmacy 1 on May 17, 2018. By way of further response, Defendants state that Pharmacy 1 continued to contest the termination decision and Defendants continued to conduct additional due diligence.

322. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

323. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

324. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations

purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

325. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

326. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

327. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in the first sentence purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents. Defendants deny all remaining allegations.

328. Denied as stated. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required,

Defendants admit only that Pharmacy 1's ability to purchase controlled substances was terminated on or about July 26, 2018.

329. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret a letter to the DEA, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the letter for a complete and accurate description of its contents.

330. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

331. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

332. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

333. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations



purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

334. Denied. The allegations in this paragraph are based upon and purport to characterize and interpret ICS's distribution data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the distribution data for a complete and accurate description of its contents.

335. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

336. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret suspicious order reporting records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

337. Denied.

338. Denied. Defendants lack knowledge or information about the nature or basis for Plaintiff's purported profitability calculations. Accordingly, those allegations are deemed to be denied.

339. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

340. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, the allegations purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

341. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

342. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, the allegations in this

paragraph purport to characterize and interpret ICS's order data and suspicious order reporting data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to that data for a complete and accurate description of their contents.

343. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

344. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

345. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

346. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

347. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

348. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

349. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

350. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

351. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the

Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

352. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

353. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

354. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

355. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

356. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

357. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

358. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

359. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

360. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the

Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

361. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

362. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

363. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

364. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

365. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

366. The allegations in this paragraph relate to Pharmacy 2 which was serviced by Defendant ABDC exclusively prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required.

367. Admitted in part; denied in part. Defendants admit only that Pharmacy 3 was an independent pharmacy located in Beckley, West Virginia and a customer of ABDC. The remaining allegations in this paragraph purport to characterize and interpret ABDC's distribution data for Pharmacy 3, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the distribution data for a complete and accurate description of their contents.

368. Denied. The allegations in this paragraph purport to characterize and interpret public records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the public records for a complete and accurate description of their contents

369. Denied.

370. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's



claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

371. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

372. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

373. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

374. Denied as stated. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that an outside investigator performed a site visit on February 11, 2015, as

part of ABDC's ongoing customer due diligence program, and submitted a report on February 22, 2015.

375. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret the outside investigator's report, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the investigator's report for a complete and accurate description of its contents.

376. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret the outside investigator's report and email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the investigator's report and the email communications for a complete and accurate description of their contents.

377. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

378. Admitted in part; denied in part. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that a letter dated June 11, 2015, which speaks for itself, was sent

to Pharmacy 3 indicating an intent to terminate controlled substances sales. By way of further response, the letter stated that Pharmacy 3 had the opportunity to seek reconsideration of the termination pursuant to ABDC's policies, and consistent with that letter Pharmacy 3 retained counsel to pursue such reconsideration and submitted a response addressing issues that were raised in the above-referenced letter. Defendants deny the remaining allegations of this paragraph.

379. Admitted in part; denied in part. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that CSRA blocked Pharmacy 3's ability to purchase controlled substances effective December 7, 2015, and incorporate by reference their response to paragraph 378, above. Defendants deny the remaining allegations of this paragraph.

380. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph are based upon and purport to characterize and interpret ABDC's distribution data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the distribution data for a complete and accurate description of its contents.

381. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

382. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

383. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

384. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

385. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, the allegations purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

386. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report

suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

387. Admitted in part; denied in part. Defendants admit only that Pharmacy 4 is an independent pharmacy located in Gainesville, Florida and was a customer of ABDC. The remaining allegations in this paragraph purport to characterize and interpret ABDC's distribution data for Pharmacy 4, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the distribution data for a complete and accurate description of their contents.

388. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret ABDC's order monitoring program and suspicious order reporting records for Pharmacy 4, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

389. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

390. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

391. Denied as stated. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that an outside investigator performed a site visit on June 21, 2017, as part of ABDC's ongoing customer due diligence program, and submitted a report on July 3, 2015.

392. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret the outside investigator's report, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the investigator's report for a complete and accurate description of its contents.

393. Denied as stated. Defendants admit only that Pharmacy 4 was an ABDC customer for controlled substances until ABDC terminated Pharmacy 4's ability to purchase controlled substances on or about December 5, 2019 and that during that time period, Pharmacy 4 remained registered by the DEA to purchase controlled substances. Defendants deny all remaining allegations in this paragraph.

394. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret distribution and suspicious order reporting records for Pharmacy 4, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

395. Admitted in part; denied in part. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that Pharmacy 4 was sent a termination letter dated May 25, 2018. Defendants deny all remaining allegations in this paragraph.

396. Denied as stated. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit that Pharmacy 4's ability to purchase controlled substances from ABDC was blocked on or about May 29, 2018 and reinstated on June 22, 2018, after Pharmacy 4 sought reconsideration and while CSRA carried out additional due diligence.

397. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for

themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

398. Admitted in part; denied in part. Defendants admit only that CSRA terminated Pharmacy 4's ability to purchase controlled substances on or about December 5, 2019. The allegations regarding ABDC's sales to Pharmacy 4 purport to characterize and interpret ABDC's distribution data, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the distribution data for a complete and accurate description of their contents. Defendants deny all remaining allegations in this paragraph.

399. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret distribution and suspicious order reporting records for Pharmacy 4, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

400. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent that a response is required, Defendants deny the allegations in this paragraph.

401. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.



402. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

403. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

404. Admitted.

405. Admitted in part; denied in part. Defendants admit only that Pharmacy 5 was an ABDC customer for controlled substances. The remaining allegations in this paragraph purport to characterize and interpret ABDC's distribution data for Pharmacy 5, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the distribution data for a complete and accurate description of their contents. Defendants deny all remaining allegations in this paragraph.

406. Denied. Defendants lack knowledge or information sufficient to form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

407. Denied. Defendants lack knowledge or information sufficient to form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

408. Denied. Defendants lack knowledge or information sufficient to form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

409. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief regarding the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

410. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

411. Denied. The allegations in this paragraph purport to characterize and interpret ABDC's distribution data for Pharmacy 5, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to distribution data for a complete and accurate description of their contents.

412. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret ABDC's distribution data, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the distribution data for a complete and accurate description of their contents.

413. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

414. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

415. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

416. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

417. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph. Accordingly, those allegations are deemed to be denied.

418. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's

claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

419. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that an outside investigator performed a site visit in April 2015, as part of ABDC's ongoing customer due diligence program, and submitted a report. Defendants deny all remaining allegations in this paragraph.

420. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret the outside investigator's report, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the investigator's report for a complete and accurate description of its contents. Defendants deny all remaining allegations in this paragraph.

421. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that a termination letter dated June 22, 2015 was sent to Pharmacy 5, which is in writing and speaks for itself. Accordingly, Defendants deny the allegations in this paragraph purporting to

characterize and interpret the letter and respectfully refer the Court to the letter for a complete and accurate description of its contents. Defendants deny all remaining allegations in this paragraph.

422. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

423. Admitted in part; denied in part. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants admit only that that Pharmacy 5 submitted a detailed letter providing dispensing information and explanation and context related to its purchasing history, and licensed physicians also submitted letters explaining the devastating impact terminating Pharmacy 5 would have on their patients. Defendants deny all remaining allegations in this paragraph.

424. Denied. The allegations in this paragraph purport to characterize and interpret public records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the public records for a complete and accurate description of their contents.

425. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

426. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's

claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the email communications for a complete and accurate description of their contents.

427. Denied. To the extent a response is required, the allegations purport to characterize and interpret written correspondence, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the written correspondence for a complete and accurate description of its contents.

428. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations purport to characterize and interpret distribution and suspicious order reporting records for Pharmacy 5, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

429. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

430. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, the allegations purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response,

Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

431. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

432. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

433. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

434. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required.

435. Denied. The allegations in this paragraph purport to characterize and interpret at least one written presentation made by ABC to the DEA, which is in writing and speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the presentation for a complete and accurate description of its contents. To the extent that the allegations refer to representations made on "multiple occasions," Defendants lack knowledge or information sufficient to form a belief regarding the truth of those allegations because the alleged representations are not sufficiently identified. Accordingly, those allegations are deemed to be denied.

436. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, the allegations in the first sentence are denied. The allegations in the second sentence are based upon and purport to characterize and interpret "written guidance," which speaks for itself. Accordingly, Defendants deny those allegations and respectfully refer the Court to the "written guidance" for a complete and accurate description of its contents.

437. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

438. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

439. Denied. The allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

440. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response



is required. To the extent a response is required, the allegations purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

441. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, the allegations purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

442. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

443. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's

claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

444. Denied.

445. Denied.

446. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. By way of further response, there is no legal requirement to maintain documentation.

447. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

448. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph. By way of further response, Defendants incorporate their responses to the purported "examples" below.

449. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

450. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report

suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

451. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph. To the extent a response is required, the allegations purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

452. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. Moreover, they mischaracterize the workings of the ROMP.

453. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

454. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, the allegations purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

455. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

456. Denied. The allegations in this paragraph purport to characterize and interpret public records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the public records for a complete and accurate description of their contents.

457. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's

claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required Defendants deny the allegations in this paragraph.

458. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required Defendants deny the allegations in this paragraph.

459. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required Defendants deny the allegations in this paragraph.

460. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. To the extent a response is required, Defendants deny the allegations in this paragraph.

461. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret order monitoring program records, which are in writing and speak for

themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

462. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

463. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

464. Denied. The allegations in this paragraph purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

465. Denied. The allegations in this paragraph purport to characterize and interpret public records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the public records for a complete and accurate description of their contents.

466. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

467. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

468. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, the allegations purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves.

Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

469. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

470. Denied. The allegations in this paragraph relate to orders prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, the allegations purport to characterize and interpret order monitoring program records and email communications, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records and email communication for a complete and accurate description of their contents.

471. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.



472. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

473. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

474. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

475. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. By way of further response, Defendants deny that comments made in order monitoring

records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

476. Denied. The allegations in this paragraph purport to characterize and interpret public records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the public records for a complete and accurate description of their contents.

477. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. By way of further response, Defendants deny that comments made in order monitoring records reflect all the steps that may have been taken or conclusions reached when an investigator reviews an order.

478. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

479. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

480. Denied. The allegations in this paragraph relate to orders prior to October 24, 2018. Pursuant to the Motion to Dismiss Ruling, the Court has dismissed all of Plaintiff's claims for civil

penalties arising prior to October 24, 2018. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

481. Denied. By way of further response, Defendants incorporate their responses to the purported “examples” above.

482. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff’s claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

483. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff’s claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

484. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff’s claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

485. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff’s claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and

conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

486. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

487. Denied. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Defendants state that Defendants were aware of the requirements set forth in 21 C.F.R. §1301.74(b). By way of further response, Defendants state that, despite repeated requests from other government entities, the industry, and Defendants, the DEA has failed to provide any meaningful guidance to Defendants or the industry overall on what constitutes an order of "unusual size" or "unusual frequency" or an order "deviating substantially from a normal pattern."

488. Denied.

489. Denied.

490. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

491. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

492. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

493. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

494. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is

required. To the extent a response is required, the allegations in this paragraph purport to characterize and interpret order monitoring program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to those records for a complete and accurate description of their contents.

495. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

496. Denied. The allegations in this paragraph relate to an order prior to October 24, 2018. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Accordingly, these allegations have been dismissed and no response is required. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

497. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

498. Denied. The allegations in this paragraph purport to characterize and interpret order monitor program records, which are in writing and speak for themselves. Accordingly, Defendants deny those allegations and respectfully refer the Court to the records for a complete and accurate description of their contents.

499. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

500. Denied. The allegations in this paragraph contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

501. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

502. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

503. Defendants repeat and reallege their responses to the corresponding allegations, as if fully set forth herein.

504. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

505. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

506. Denied. To the extent this paragraph seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed plaintiff's claim for civil penalties prior to that date. Moreover, the allegations contain legal arguments and conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

Defendants deny the allegations contained in the Prayer for Relief. To the extent the Prayer for Relief seeks to impose liability based on alleged failure to report suspicious orders prior to October 24, 2018, the Court has dismissed Plaintiff's claim for civil penalties prior to that date. To the extent the allegations contained in the Prayer for Relief set forth legal arguments and legal conclusions, no response is required. Further answering, Defendants admit only that Plaintiff purports to seek the relief identified in the Prayer for Relief, but deny that Plaintiff is entitled to any relief that it seeks. Except as specifically admitted herein, Defendants deny the remaining allegations in the Prayer for Relief.

### **AFFIRMATIVE DEFENSES**

By asserting the defenses set forth below, Defendants do not allege or admit that they have the burden of proof and/or the burden of persuasion with respect to any of these defenses. All of the following defenses are pled in the alternative and none constitutes an admission that Defendants are in any way liable to Plaintiff or that Plaintiff is entitled to any relief whatsoever. Defendants reserve the right to amend or supplement their defenses as discovery progresses.



**First Defense – Failure to State a Claim**

1. The Complaint fails to state a claim upon which relief can be granted.

**Second Defense – Waiver**

2. Plaintiff's claims are barred, in whole or in part, by waiver.
3. DEA is a subdivision of the DOJ.
4. Defendants submitted suspicious order reports to DEA.
5. Throughout the time period relevant to the Complaint (and in the years prior), DEA has formally audited Defendants' distribution centers routinely and repeatedly. These audits often specifically assessed Defendants' diversion control programs, including Defendants' suspicious order monitoring and reporting programs, policies, and procedures.

6. The purpose of DEA audits includes confirming that registrants (1) are maintaining effective controls against diversion; and (2) have designed and are operating a system to disclose to the registrant suspicious orders of controlled substances, such that they may be reported to DEA.

7. Each year during the relevant period, following these audits of Defendants' distribution centers and/or diversion control programs, DEA always has renewed Defendants' DEA registrations. When considering whether to issue or renew such a registration, DEA must take into account whether doing so is consistent with the public interest. In making the public interest determination, DEA was required to consider whether Defendants maintained effective controls against diversion. 21 U.S.C. § 823(b)(1).

8. DEA never has communicated any audit findings to Defendants consistent with the allegations of non-compliance now asserted in the Complaint. More specifically, DEA never communicated an audit finding to Defendants that Defendants should report as suspicious more or different orders to DEA. DEA also never communicated an audit finding to Defendants that all

orders flagged by Defendants' order monitoring programs for further human review (i.e., "orders of interest") should be reported as suspicious or that Defendants needed to "dispel the suspicion" for all such orders of interest.

9. DEA, a subdivision of the DOJ, was aware of the way that Defendants' programs operated, including the aspects of Defendants' program that Plaintiff now alleges in the Complaint to be deficiencies in those programs.

10. DEA, as a subdivision of the DOJ, is authorized to waive claims on behalf of Plaintiff pursuant to the authorities that the Attorney General delegated to the DEA and/or its Administrator.

11. By continuing to renew Defendants' DEA registrations, Plaintiff intended to waive and did waive its right to seek penalties for any alleged deficiencies with Defendants' order monitoring programs or suspicious order reporting.

12. In support of this affirmative defense, Defendants also hereby incorporate by reference all allegations stated in support of the above- and below-referenced affirmative defenses.

### **Third Defense – Estoppel**

13. Plaintiff's claims are barred, in whole or in part, by estoppel.

14. DEA is a subdivision of the DOJ.

15. As stated, throughout the relevant period (and in the years prior), DEA regularly and repeatedly audited Defendants' distributions centers and continuously renewed Defendants' DEA registrations.

16. At the time, DEA was aware of: (1) the volume of controlled substances Defendants were distributing, including through other forms of continuous, regular reporting that Defendants were making to DEA (i.e., ARCOS reporting); (2) the design and operation of Defendants'

suspicious order reporting programs, policies, and procedures; and (3) the number of suspicious orders reported by Defendants.

17. In addition, DEA personnel never indicated to Defendants that Defendants should either report all orders of interest or “dispel the suspicion” for all orders of interest. To the contrary, DEA represented to Defendants that they should *not* report all orders of interest to DEA as suspicious, and that Defendants should only report “truly suspicious” orders based on the exercise of Defendants’ judgment.

18. Defendants reasonably relied on these representations and the further indications that DEA believed Defendants were in compliance with the relevant regulatory requirements, including DEA’s consistent re-registration of Defendants’ distribution centers with access to all of the above-referenced information, as confirmation that their order monitoring programs indeed did comply with applicable CSA provisions and DEA regulations.

19. In light of the above actions and statements by DEA, Defendants would be materially prejudiced if Plaintiff were now successful in penalizing Defendants for engaging in alleged conduct Plaintiff only now claims did not actually comply with the CSA and/or related DEA regulations.

20. In support of this affirmative defense, Defendants also hereby incorporate by reference all allegations stated in support of the above- and below-referenced affirmative defenses.

#### **Fourth Defense – Entrapment By Estoppel**

21. Plaintiff’s claims are barred, in whole or in part, by the doctrine of entrapment by estoppel.

22. To the extent Defendants are found to have negligently failed to report suspicious orders, as alleged in the Complaint, they did so based on and because of their reasonable reliance on the affirmative advice of an authorized agent of Plaintiff.

23. As stated above, DEA personnel represented to Defendants that Defendants should not report to DEA as suspicious all orders of interest, and instead that Defendants should only report “truly suspicious” orders based on the exercise of Defendants judgment.

24. In addition, by renewing the Defendants’ DEA registrations each year, DEA, a subdivision of the DOJ, indicated that Defendants’ order monitoring programs, policies, and procedures complied with the CSA and DEA regulations.

25. Defendants reasonably and in good faith relied upon DEA’s representations.

26. In support of this affirmative defense, Defendants also hereby incorporate by reference all allegations stated in support of the above- and below-referenced affirmative defenses.

#### **Fifth Defense – Acquiescence**

27. Plaintiff’s claims are barred, in whole or in part, by the doctrine of acquiescence.

28. At all relevant times, DEA has been and continues to be fully aware of the design and operation of Defendants’ order monitoring programs, including the number of suspicious orders reported by Defendants and the details of those orders (e.g., the customer, the product at issue, the volume ordered, etc.).

29. Despite Plaintiff’s recent allegation that the Defendants’ order monitoring programs have been deficient and out of compliance with applicable law since at least 2014, Plaintiff did not take any action to penalize Defendants until nearly ten years later, when it initiated this suit.

30. Moreover, since at least 2014, Plaintiff has acted in a manner inconsistent with its current position based on DEA's continual renewal of Defendants' DEA registrations, despite being aware of the aspects of Defendants' order monitoring programs and suspicious order reporting Plaintiff now alleges demonstrate alleged violations of the CSA.

31. In support of this affirmative defense, Defendants also hereby incorporate by reference all allegations stated in support of the above- and below-referenced affirmative defenses.

**Sixth Defense – Fifth Amendment Due Process**

32. Discovery and a complete factual record will demonstrate that Plaintiff's claims are barred, in whole or in part, because Plaintiff seeks to penalize Defendants based on the application of a law that purports to impose impermissibly vague and imprecise legal obligations, including the impermissibly vague and imprecise term "suspicious order," in such a way that violates the Due Process Clause in the Fifth Amendment to the Constitution of the United States.

**Seventh Defense – Retroactive Application of Law**

33. Plaintiff's claims are barred, in whole or in part, because they are based on a theory that improperly applies governing law retroactively.

**Eighth Defense – Eighth Amendment Excessive Fines**

34. Plaintiff seeks penalties that, if imposed, would violate the Excessive Fines Clause in the Eighth Amendment to the Constitution of the United States.

**Ninth Defense – Paperwork Reduction Act**

35. Plaintiff's claims are barred because the DEA has never complied with the Paperwork Reduction Act

36. The DEA has never obtained approval under the Paperwork Reduction Act for the reporting obligations DEA purported to impose in the suspicious order reporting regulation and/or any implicit amendments to that rule by way of DEA adjudications and/or other orders.

37. Separately, the DEA has never obtained approval under the Paperwork Reduction Act for any purported recordkeeping requirements related to suspicious order monitoring and reporting. Thus, to the extent Plaintiff seeks to impose liability on Defendants based on a lack of order investigation documentation, such claims are legally barred.

38. DEA's failure to obtain the required approvals under the Paperwork Reduction Act and implementing OMB regulations affords Defendants a "complete defense" as a matter of law. 44 U.S.C. § 3512(b).

#### **DEMAND FOR JURY TRIAL**

Defendants hereby demand a trial by jury of all issues so triable pursuant to Rule 38 of the Federal Rules of Civil Procedure.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Defendants specifically deny any liability or wrongdoing whatsoever, deny that Plaintiff is entitled to any relief that it seeks, and demand judgment in Defendants favor and against Plaintiff, dismissing the Complaint in its entirety, with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

Respectfully submitted,

/s/ Robert A. Nicholas

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**CERTIFICATE OF SERVICE**

I hereby certify that on December 18, 2023, I served a true and correct copy of the foregoing upon all counsel of record via the Court's CM/ECF electronic filing system.

/s/ Robert A. Nicholas

Robert A. Nicholas